IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Breitenbach, A., *et al.*
Serial No.:	**10/523,908**
Filed:	January 28, 2005
Title:	HOT MELT TTS FOR ADMINISTERING ROTIGOTINE
Group Art Unit:	1615
Examiner:	H.S. Ahmed
Confirmation No.:	9463
Docket No.:	**6102-000075/US/NP**
Client Ref.:	P/Brt/I/5/02

SUBMITTED ELECTRONICALLY VIA EFS-WEB

January 22, 2009

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO NOTICE OF NON-COMPLIANT AMENDMENT

This paper is responsive to the Notice of Non-Compliant Amendment dated January 6, 2009, in which a shortened statutory period of one month was set. This response is timely and no fee for extension of time is believed payable.

If any fee should nonetheless be found to be required, please charge the amount of such fee to Deposit Account No. 08-0750.

The Notice alleges that Applicant's reply of September 18, 2008 is not fully responsive in omitting to include substantive arguments directed to rejection for obviousness-type double patenting. Applicant notes that each of the six obviousness-type double patenting rejections made in the prior Action dated May 28, 2008 was provisional.

This paper includes replacement for Section 4 of Applicant's response of September 18, 2008, *viz.*, Applicant's response to the six provisional obviousness-type double patenting rejections. When this paper is considered together with Applicant's submission of September 18, 2008, a full response will be seen to have been made to the May 28, 2008 Action.

4. Obviousness-type double patenting

Claims 28–37 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over Claims 1–23 of co-pending U.S. application Serial No. 10/630,633 ('633).

Claims 28–37 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over Claims 15–36 of copending U.S. application Serial No. 10/139,894 ('894).

Claims 28–37 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over Claim 12 of copending U.S. application Serial No. No. 10/140,096 ('096).

Claims 28–37 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over Claims 1–6 of copending U.S. application Serial No. 10/139,894 ('894).

Claims 28–37 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1–120 of copending U.S. application Serial No. 11/239,701 ('701).

Claims 28–37 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1–110 of copending U.S. application Serial No. 11/239,772 ('772).

Each of these rejections is provisional because the allegedly conflicting claims in each case have not yet been patented. It is further noted that even if the present claims do conflict, ongoing prosecution of the reference application may in each case result in amendments that would obviate the present double patenting rejection.

Applicant believes the purpose of a provisional double patenting rejection is as set forth in MPEP 804.I.*B*, which states (citations omitted; emphasis added) "... the courts have sanctioned the practice of making applicant aware of the potential double patenting problem if one of the applications became a patent by permitting the examiner to make a "provisional" rejection on the ground of double patenting. The merits of such a provisional rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue."

Applicant thanks the Examiner for drawing Applicant's attention to the potential double patenting issues that allegedly would apply if any of the reference applications cited above became a patent, by issuing a series of provisional double patenting rejections in accordance with MPEP 804.I.*B*. While the merits of these provisional rejections "can be addressed" by Applicant at this stage, MPEP 804.I.*B* places no obligation on Applicant to address the merits while the rejections remain provisional. Applicant's obligation under 37 C.F.R. §1.111(b) to "reply to every ground of objection and rejection in the prior office action" is not seen by Applicant to extend to substantive argument directed to provisional rejections that, as noted above, could be obviated by ongoing prosecution of the reference applications. Applicant acknowledges that once the present claims have been found to be otherwise allowable and/or a reference application issues as a patent, any obviousness-type double patenting rejection that is still maintained will need to be addressed, either through traverse with substantive argument or by filing a terminal disclaimer.

However, without admission that any substantive argument (or terminal disclaimer) to overcome a provisional double patenting rejection is necessary at this time, Applicant elects to make the following observations in the interest of advancing prosecution.

Claim 28 of the present application, from which all other claims presently in consideration depend, contains the limitation that the hot-meltable adhesive component of the TTS matrix is one "exhibiting at 160°C a dynamic viscosity of not more than 100 Pa.s." This limitation is not found in any reference claim applied in the present rejection. No rationale is presented in the Action dated May 28, 2008 for one of ordinary skill in the art to modify any reference claim to add this limitation.

The importance of a suitably low dynamic viscosity (as presently claimed, not greater than 100 Pa.s) at 160°C is explained in the present specification, for example at pp. 11–12 thereof. In essence, rotigotine has been found by the present inventors to be stable under short-term heating to 160°C and to lend itself well to hot-melt processing up to that temperature (specification, p. 8, last two paragraphs). Many adhesives are not suitable for processing by the hot-melt method at temperatures up to 160°C because of excessively high viscosity at such temperatures. The selection of an adhesive system having a viscosity not

greater than 100 Pa.s at 160°C for use with rotigotine is non-obvious over the claims of each of the reference applications. Each of the present provisional obviousness-type double patenting rejections is traversed at least on this ground and withdrawal of all of the above rejections is respectfully requested.

Respectfully submitted,

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